

14. (New) A process for the preparation of a rapidly disintegrating solid dosage form, said dosage form consisting essentially of primary particles of a water-insoluble or poorly water-soluble solid drug dispersed throughout a support matrix, said support matrix consisting of a bulking/releasing agent or a mixture of bulking and releasing agents, wherein each primary particle is stabilized with one or more surface modifiers of which at least one is a phospholipid adsorbed on to the surface thereof, and wherein said matrix dissolves or substantially disperses in a rapid disintegration time when introduced into an aqueous environment to release said primary particles into said aqueous environment without irreversible aggregation and/or agglomeration and without particle size growth, said process consisting of the steps of:

- a) admixing an aqueous homogeneous suspension of micronized primary particles of a water-insoluble or poorly water-soluble drug with a matrix-forming bulking/releasing agent or a mixture of matrix-forming bulking and releasing agents, wherein said suspension has a dispersity with volume weighted mean particle size from 0.2 micrometers to 5 micrometers, said particles are stabilized by the presence of one or more surface modifier of which at least one is a phospholipid adsorbed on to the surface thereof, and said matrix-forming agent or agents are present in an amount sufficient to allow drying of said suspension without irreversible aggregation and/or agglomeration; then,
- b) drying the suspension and bulking/releasing agent mixture of step (a) to produce a support matrix as a dried material containing said primary particles; then,
- c) optionally coarse milling and blending said dried material with one or more pharmaceutically acceptable excipients to provide a dried powder; and then,
- d) forming said dried material or said dried powder into said solid dosage form.

15. (New) A process for the preparation of a rapidly disintegrating solid dosage form, said dosage form consisting essentially of primary particles of a water-insoluble or poorly water-soluble solid drug dispersed throughout a support matrix, said support matrix consisting of a bulking/releasing agent or a mixture of bulking and releasing agents, wherein each primary particle is stabilized with one or more surface modifier of which at least one is a phospholipid adsorbed on to the surface thereof, and wherein said matrix dissolves or substantially disperses in a rapid disintegration time when introduced into an aqueous environment to release said primary particles into said aqueous environment without irreversible aggregation and/or agglomeration and without particle size growth, said process consisting of the steps of:

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cont.
- a) admixing an aqueous homogeneous suspension of micronized primary particles of a water-insoluble or poorly water-soluble drug with a matrix-forming bulking/releasing agent or a mixture of matrix-forming bulking and releasing agents, wherein said suspension has a dispersity with volume weighted mean particle size from 0.2 micrometers to 5 micrometers, said particles are stabilized by the presence of one or more surface modifiers of which at least one is a phospholipid adsorbed on to the surface thereof, and said matrix-forming agent or agents are present in an amount sufficient to allow drying of said suspension without irreversible aggregation and/or agglomeration; then,
 - b) distributing the suspension and bulking/releasing agent mixture of step (a) into unit dosage form molds; and then,
 - c) freeze-drying the suspension and bulking/releasing agent mixture in said unit dosage form molds.

16. (New) The process of claim 14 or 15, wherein the matrix-forming bulking/releasing agent is selected from pharmaceutically acceptable saccharides, polysaccharides, humectants, natural polymers, synthetic polymers, inorganic additives, and cellulose based polymers.

17. (New) The process of claim 16, wherein the saccharide or polysaccharide is selected from mannitol, trehalose, lactose, sucrose, sorbitol, maltose, and combinations thereof.

18. (New) The process of claim 16, wherein the humectant is selected from glycerol, propylene glycol, polyethylene glycol, and combinations thereof.

19. (New) The process of claim 16, wherein the polymer is selected from gelatin, dextran, starch, polyvinylpyrrolidone, a poloxamer, a pharmaceutically acceptable synthetic acrylate polymer, and combinations thereof.

20. (New) The process of claim 16, wherein the inorganic additive is selected from colloidal silica, tribasic calcium phosphate, a pH buffering salt, and combinations thereof.

21. (New) The process of claim 16, wherein the cellulose based polymer is selected from microcrystalline cellulose, hydroxymethyl cellulose, hydroxypropyl cellulose, methylcellulose, and combinations thereof.

22. (New) The process of claim 14 or 15, wherein the rapid disintegration time is less than 2 minutes.

23. (New) The process of claim 14 or 15, wherein the rapidly dispersing solid dosage form further contains an effervescent agent, a binding agent, a flavor, a polymeric coating on the external surface of the dosage form, a color or combinations thereof.

24. (New) The process of claim 14 or 15, wherein the drug is selected from the group consisting of antifungal agents, immunosuppressive agents, immunoactive agents, antiviral agents, antineoplastic agents, analgesic agents, anti-inflammatory agents, antibiotic agents, antiepileptic agents, anesthetic agents, hypnotic agents, sedative agents,

antipsychotic agents, neuroleptic agents, antidepressant agents, anxiolytic agents, anticonvulsant agents, antagonist agents, neuron blocking agents, anticholinergic agents, cholinomimetic agents, antimuscarinic agents, muscarinic agents, antiadrenergic agents, antarrhythmic agents, antihypertensive agents, hormones, and nutrients.

25. (New) The process of claim 14 or 15, wherein the drug is fenofibrate, itraconazole, or cyclosporine.

26. (New) The process of claim 14 or 15, wherein the phospholipid is selected from a natural phospholipid, a synthetic phospholipid, a semisynthetic phospholipid, a synthetic phospholipid, and combinations thereof.

27. (New) The process of claim 26, wherein the natural phospholipid is an egg phospholipid, a soybean phospholipid, or a combination thereof.

28. (New) The process of claim 26, wherein the phospholipid is salted, desalted, hydrogenated, or partially hydrogenated.

29. (New) The process of claim 26, wherein the phospholipid is Phospholipon 100H, Lipoid E80, phosphatidylcholine, phosphatidylethanolamine, phosphatidylserine, phosphatidylinositol, phosphatidylglycerol, phosphatidic acid, a lysophospholipid, or a combination thereof.

30. (New) The process of claim 14 or 15, wherein the surface modifier is selected from pharmaceutically acceptable natural surfactants, nonionic surfactants, anionic surfactants, cationic surfactants, and colloidal clays.

31. (New) The process of claim 30, wherein the pharmaceutically acceptable natural surfactant is casein, gelatin, tragacanth, a wax, an enteric resin, paraffin, acacia, cholesterol, or a combination thereof.

32. (New) The process of claim 30, wherein the nonionic surfactant is a pharmaceutically acceptable polyoxyethylene fatty alcohol ether, a sorbitan fatty acid ester, a polyoxyethylene fatty acid ester, a sorbitan ester, glycerol monostearate, a polyethylene glycol, cetyl alcohol, cetostearyl alcohol, stearyl alcohol, a poloxamer, a polaxamine, methylcellulose, hydroxycellulose, hydroxypropylcellulose, hydroxypropylmethylcellulose, noncrystalline cellulose, or a combination thereof.

33. (New) The process of claim 30, wherein the anionic surfactant is potassium laurate, triethanolamine stearate, sodium lauryl sulfate, an alkyl polyoxyethylene sulfate, sodium alginate, sodium deoxycholate, dioctyl sodium sulfosuccinate, negatively charged glyceryl esters, sodium carboxymethylcellulose, calcium carboxymethylcellulose, or a combination thereof.

34. (New) The process of claim 30, wherein the cationic surfactant is a pharmaceutically acceptable quaternary ammonium compound selected from the group consisting of benzalkonium chloride, cetyltrimethylammonium bromide, lauryldimethylbenzylammonium chloride, and a combination thereof.

35. (New) The process of claim 30, wherein the colloidal clay is bentonite or veegum or a combination thereof.

36. (New) The process of claim 14, wherein the suspension is dried by spray drying, spray coating, freeze-drying or lyophilization.

37. (New) The process of claim 14 or 15, wherein the micronized primary particles are prepared in a particle fragmentation process.

38. (New) The process of claim 37, wherein the particle fragmentation process is sonication, milling, homogenization, microfluidization, or antisolvent and solvent precipitation.

39. (New) The process of claim 14, wherein the pharmaceutically acceptable excipient is a tableting aid for compression, a glidant for hard gelatin encapsulation, an effervescent disintegration agent, a dispersant for a dry powder inhaler, or a combination thereof.

40. (New) The process of claim 14 or 15, wherein the dosage form is a tablet, a gelatin encapsulation, or a powder.

41. (New) The process of claim 14 or 15, wherein the surface modifier is present between 0.5% w/w and 50% w/w. E

42. (New) The process of claim 14 or 15, wherein the amount of matrix-forming agent is between 0.1% w/w and 90% w/w.

43. (New) The process of claim 14 or 15, wherein the drug is present between 0.1% w/w and 60% w/w.

44. (New) The process of claim 14 or 15, wherein the suspension contains less than 10% by weight of aggregated primary particles.

45. (New) The process of claim 14 or 15, wherein the suspension contains less than 1% by weight of aggregated primary particles.

46. (New) The process of claim 31, wherein the aggregated primary particles can be deaggregated by application of physical agitation.

47. (New) The process of claim 22, wherein the aggregated primary particles can be deaggregated by application of physical agitator.

48. (New) A dosage form prepared by the process of claim 15.

49. (New) A dosage form prepared by the process of claim 14.

Attached: Declaration of Awadhesh Mishra made August 8, 2001.